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| APPLICATION NO. | FI | LING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------------------------------|-----------------------|------------|----------------------|---------------------|------------------|
| 09/868,515 | 09/868,515 06/18/2001 | | Klaus Schelberger | 49651 1391 | |
| 26474 | 7590 | 03/09/2004 | , | EXAM | IINER |
| KEIL & W | | | JIANG, SHAOJIA A | | |
| 1350 CONNECTICUT AVENUE, N.W. WASHINGTON, DC 20036 | | | | ART UNIT | PAPER NUMBER |
| | | | | 1617 | |

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|--------------------|--|--|--|--|
| Office Action Summany | 09/868,515 | SCHELBERGER ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Shaojia A Jiang | 1617 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 10 De | Responsive to communication(s) filed on 10 December 2003. | | | | | |
| 2a) This action is FINAL . 2b) This | This action is FINAL . 2b) This action is non-final. | | | | | |
| | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4) ☐ Claim(s) 12-23 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 12-23 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) | | | | | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4) Interview Summary (Paper No(s)/Mail Da | | | | | |
| Notice of Dransperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date | 5) Notice of Informal Pa | | | | | |

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DETAILED ACTION

This Office Action is a response to Applicant's response filed on December 10, 2003 wherein no claims have been amended. It is noted that claims 1-11 have been cancelled in the Applicant's previous amendments April 28, 2003 and December 2, 2002

Currently, claims 12-23 are pending in this application.

It is recorded that Applicant's election without traverse of the invention of the species of compounds la and II 79, submitted April 30, 2001.

The claims have been examined insofar as they read on the elected specie.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-23 are rejected under 35 U.S.C. 112, first paragraph, for lack of scope of enablement, of record in the previous Office Action July 15, 2003.

Applicant's remarks filed December 10, 2003 with respect to this rejection of claims 12-23 made under 35 U.S.C. 112, first paragraph of record have been fully considered but are not deemed persuasive to remove the rejection as discussed further below.

Applicant's remarks and assertion in the declaration of Dr. Eberhard

Ammermann (submitted January 29, 2002) that the data from testing of compounds <u>Ia</u>,

<u>Ib and Ic in combination with a single compound IIa</u>, e.g., "Degree of action observed"

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compared with "Degree of action calculated", in Ammermann's declaration at page 4, demonstrates the claimed combination herein shows unexpected and synergistic activity against fungi, has been fully considered but not deemed persuasive to remove the rejection. As discussed in the previous Office Action, synergistic or superadditive effects for combinations of compounds are highly unpredictable. First, only one single particular compound IIa of Formula II was tested among numerous compounds covered by the Formula (II) such as 101 compounds disclosed in Table 1 of the specification at page 6-8. Thus, the evidence in the examples is also not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the ingredients in the claimed composition. See MPEP § 716.02(d). Since any structural variation to a compound, i.e., different substituents to a compound and/or at different positions of a compound, would be reasonably expected to alter its properties, one of ordinary skill would be required to perform undue experimentation to determine which, if any, e.g., at least the other 100 compounds covered by the formula, would be useful in the claimed fungicidal composition.

Moreover, one of ordinary skill in the art would clearly recognize that the structure of compound (Id) differs by a significant structural feature from compounds Ia, Ib, and Id which have a morpholine ring (1,4-oxazine) or a piperidine ring, whereas compound Id contains no morpholine ring (1,4-oxazine) or piperidine ring. Thus, the activity and properties of compound (Id) would be reasonably expected to separate and distinct from compounds Ia, Ib and Ic.

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Secondly, these results, "Degree of action observed" of compounds Ia, Ib and Ic in combination with a single compound IIa, appear generated merely from one shot, not from the statistic results. Thus, the accuracy and reliability of these results are in question.

Thus, synergistic or superadditive effects for any combinations of compounds encompassed herein are <u>highly unpredictable</u> as discussed above and in the previous Office Action.

Therefore, the declaration of Dr. Eberhard Ammermann (submitted January 29, 2002) is not seen to be effective and sufficient to demonstrate <u>any</u> synergistic effects produced by any combinations encompassed herein.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

The evidence in the declaration and specification is not seen to show clear and convincing synergy for any combination of agents within the claims. Therefore, in view of the unpredictability of such synergistic effects of the claimed combination discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in <u>undue experimentation</u> to test all compounds encompassed in the instant claims and their combinations, with no assurance of success.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwalge et al. (WO 97/06681, of record) and Kasahara et al. (WO 96/19442, of record) of record in the previous Office Action July 15, 2003.

Schwalge et al. (WO 97/06681 equivalent to US 5,972,941) discloses that the particular morpholine, Ila therein, (the elected species, Ia, herein), alone or in combination with the oxime compound of formula I therein in synergistically active amounts is useful in a fungicidal composition and methods for controlling harmful fungi. See US 5,972,941: abstract, col.1 lines 10-55, and the testing at col.5-6. Schwalge et al. also discloses that the mixture therein maybe in two parts wherein one part comprises Compound I therein in a solid or liquid carrier, and the other part comprises the instant particular morpholine a solid or liquid carrier; compound I therein and the instant particular morpholine are applied simultaneously together or separately or successively (see col.2 lines 7-8, col. 3 line 33 to col.4 line 36).

Kasahara et al. (WO 96/19442, equivalent to US 5,847,005) discloses that the particular oxime derivatives such as the elected species, II 79 herein in an effective amount (see Compound 376 in US 5,847,005, col. 21-22), is useful in a fungicidal

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composition for controlling plant diseases caused by fungi. See WO 96/19442: abstract, and equivalent to US 5,847,005: abstract, col.1 lines 9-36, and col.21-22 and testing in col. 53.

Schwalge et al. and Kasahara et al. do not expressly disclose the employment of the particular oxime derivative, II 79 herein in combination with the particular morpholine, la herein, in a fungicidal composition and a method for controlling harmful fungi.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular morpholine, la herein, in combination with the particular oxime derivative, II 79 herein, in a fungicidal composition and a method for controlling harmful fungi.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular morpholine, Ia herein, in combination with the particular oxime derivative, II 79 herein, in a fungicidal composition and a method for controlling fungi, because the particular morpholine, Ia herein, alone or in combination with an oxime compound in effective amounts is known to be useful in a fungicidal composition and a method for controlling fungi based on the prior art. Moreover, the particular oxime derivative, II 79 herein, in an effective amount is known to be useful in a fungicidal composition for controlling plant diseases caused by fungi. Therefore, one of ordinary skill in the art would have reasonably expected that combining Ia herein and II 79 herein known useful for the same purpose in a fungicidal composition would improve the fungicidal effect for controlling fungi in plants.

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Since all active composition components herein are known to useful in a fungicidal composition, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Additionally, the teachings of Schwalge regarding the combination of the particular morpholine herein and the oxime compound therein known to be useful in a fungicidal composition exhibiting synergistic effects against the fungi further provides the motivation to make the present invention.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's remarks filed on December 10 with respect to this rejection made under 35 U.S.C. 103(a) as being unpatentable over Schwalge et al. and Kasahara et al. have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Applicant's data shown in Ammermann's declaration and the specification herein have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention over the prior art but are not deemed persuasive, as discussed above regarding the rejection made under 35 U.S.C. 112, first paragraph, for lack scope of enablement. Thus, the evidence in the examples is also not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the active compounds in the claimed composition. See MPEP §

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716.02(d). Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The

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fax phone number for the organization where this application or proceeding is assigned is 703.872.9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-

1235.

S. Anna Jiang, Ph.D.

Patent Examiner, AU 1617

March 6, 2004